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Indian Standard

“पुनर्विज्ञापित” 2001

SPECIFICATION FOR “RE-AFFIRMED”
NEEDLE HOLDER (GILLIES) COMBINED
WITH SCISSORS, FOR PLASTIC SURGERY

UDC 615.472.41



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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
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SPECIFICATION FOR NEEDLE HOLDER (GILLIES) COMBINED WITH SCISSORS, FOR PLASTIC SURGERY

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Indian Standard
**SPECIFICATION FOR
NEEDLE HOLDER (GILLIES) COMBINED
WITH SCISSORS, FOR PLASTIC SURGERY**

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 31 August 1967, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Consumer Products Division Council.

0.2 Work on standardization of surgical instruments has been taken up at the instance of the Advisory Committee for Development of Surgical Instruments, Equipment and Appliances of Government of India.

0.3 In the preparation of this standard, assistance has been derived from IND/GS/MED/674(b) Needle holder (Gillies) combined with scissors, 15 cm, issued by the Ministry of Defence, Government of India.

0.4 This Indian standard is one of a series on surgical instruments. Other standards published so far in the series appear on page 8.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value observed or calculated, expressing the result of a test shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers requirements for needle holder (Gillies) combined with scissors, for plastic surgery.

2. MATERIAL

2.1 The needle holder shall be made of stainless steel conforming to designation 30Cr13 of Schedule V of IS : 1570-1961† or of the composition

*Rules for rounding off numerical values (*revised*).

†Schedules for wrought steels for general engineering purposes.

IS : 4245 - 1967

given below:

<i>Element</i>	<i>Percent</i>
Carbon	0.35 to 0.45
Silicon	0.10 to 0.70
Manganese	0.30 to 0.70
Nickel	1.00 <i>Max</i>
Chromium	12.0 to 14.0

2.2 Screw shall be made of stainless steel, either the same as used for the instrument or conforming to designation 22Cr13S28 of Schedule V of IS : 1570-1961*.

3. SHAPE AND DIMENSIONS

3.1 Needle holder shall conform generally to the shape and dimensions shown in Fig. 1. When a left-handed needle holder is specifically ordered, its shape shall be a mirror image of Fig. 1.

3.2 Screw — Screw used shall be of a slotted cheese head pattern as shown in Fig. 2. The profile of the screw thread shall conform to IS : 1362-1962†. The thread shall be of such length as to allow sufficient unthreaded shank for proper bearing surface and to adequately secure component parts of the needle holder. Screw shall retain position after setting without binding or loosening during use and shall be flush with the surface of the blade.

4. WORKMANSHIP AND FINISH

4.1 The component halves shall open and close fully and freely without any undue slide-play at the joint.

4.2 The jaws shall have fine diamond pattern cross cuts. The groove in one jaw and the fenestrated portion in the other shall coincide when the jaws are closed. On closure, the jaws shall meet fully and accurately.

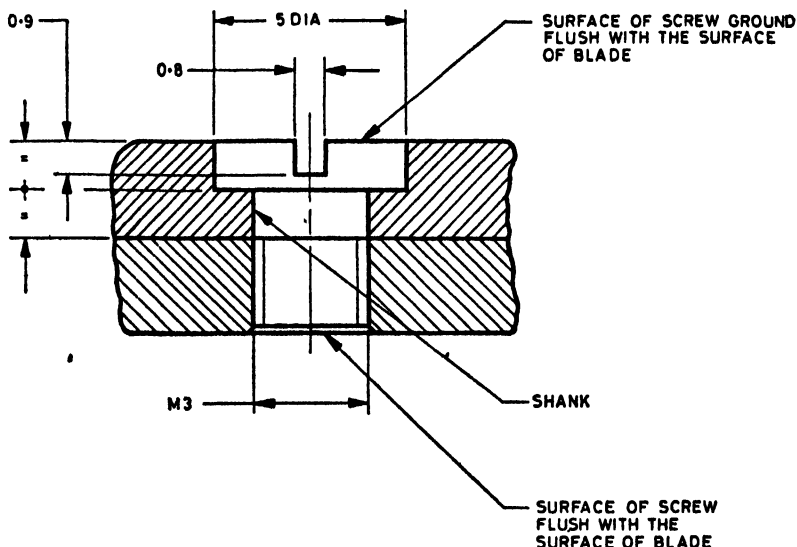
4.3 The scissors portion shall have a continuous pinch with slight cross over action.

4.4 The surface of the needle holder shall be free from cracks, seams, burrs, flaws and other defects, and shall be passivated and finished smooth and bright.

4.5 The edges shall be even and rounded, except for the cutting edge of the scissoring portion which shall be sharp. The cutting edge shall not have any feather.

*Schedules for wrought steels for general engineering purposes.

†Dimensions for screw threads for general purposes (diameter range 1.6 to 39 mm).



All dimensions in millimetres.

FIG. 2 DETAILS OF SCREW ASSEMBLY

5. HARDNESS

5.1 The needle holder shall be evenly hardened and tempered to 550 to 600 *HV*.

6. TESTS

6.1 Performance

6.1.1 A suture needle of 12 mm length, half-circle type will be gripped between the jaws and the needle shall be made to pierce a piece of soft leather 1.6 mm thick. The needle held by the jaws shall not slip.

6.1.2 The cutting edges of the scissors component from the pinch to the tips shall cut wet tissue paper, teased out cotton wool, fine hairs and frayed lint cleanly and easily.

6.2 Flexibility

6.2.1 A force of moderate degree by the fingers shall be applied to each shank attempting to bend the shank on the width. This shall be repeated at several points along the shanks. The test shall then be repeated in a plane at right angles to the first. On completion of the test, the shank shall not have acquired permanent set.

6.2.2 The terminal 12 mm of the jaws shall be made to bite on a piece of firm rubber 12 mm thick and the full pressure of both hands brought to bear on the finger loops. This test shall be repeated six times. On completion of this test, the jaws shall continue to meet accurately.

6.3 Hardness — When tested on a hardness testing machine the needle holder shall have a Vicker's diamond pyramid hardness number as specified in 5.1.

6.4 Corrosion Resistance Test — For corrosion resistance, copper sulphate test shall be carried out as given in 6.4.1.

6.4.1 Copper Sulphate Test — The sample shall be scrubbed with soap and warm water, rinsed in hot water followed by a dip in 95-percent ethyl alcohol and dried. The sample shall be completely immersed in copper sulphate solution at room temperature for six minutes and shall then be washed off with fresh water or wet cotton wool. The copper sulphate solution shall be made up as follows:

Copper sulphate ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$)	4.0 g
Sulphuric acid (H_2SO_4) (sp gr 1.84)	10.0 g
Water (H_2O)	90.0 ml

There shall be no red stains or spots on the sample after test, but the polished surface becoming dull may be permitted.

7. MARKING

7.1 Each needle holder shall be legibly and indelibly marked with the manufacturer's name, initials, or registered trade-mark. In addition, the words 'Stainless Steel' shall also be marked.

7.1.1 The needle holders may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

8. PACKING

8.1 Each needle holder shall be wrapped in moisture-proof polyethylene bag and packed in cartons in a manner that coming into contact with one another is avoided.

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INDIAN STANDARDS INSTITUTION

Headquarters

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 1

Telephones 27 36 11 - 20

Telegrams Manaksanstha

Branch Offices

Telegrams Manaksanstha

534 Sardar Vallabhbhai Patel Road	Bombay 7	Telephone	35 70 27
5 Chowringhee Approach	Calcutta 13	,,	23-18 23
117/418 B Sarvodaya Nagar	Kanpur	,,	3 76 95
54 General Patters Road	Madras 2	,,	8 72 78

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TO

**IS:4245-1967 SPECIFICATION FOR NEEDLE
HOLDER (GILLIES) COMBINED WITH
SCISSORS, FOR PLASTIC SURGERY**

Alterations

(Page 7, clauses 6.4 and 6.4.1) - Substitute the following for the existing clauses:

'6.4 Corrosion Resistance - The instrument shall satisfy the boiling and autoclaving test as mentioned in IS:7531-1975*.'

(Page 7, foot-note) - Insert the following foot-note at the bottom of the page:

'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments.'

(CPDC 11)

Reprography Unit, ISI, New Delhi.